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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,199	08/14/2006	Augusto Brazzini	EXPL-004	9591
	7590 08/01/201 OF ALAN W. CANNO	EXAMINER		
942 MESA OAK COURT			MENDOZA, MICHAEL G	
SUNNYVALE, CA 94086			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			08/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
	10/567,199	BRAZZINI ET AL.		
Office Action Summary	Examiner	Art Unit		
	MICHAEL MENDOZA	3734		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. sely filed the mailing date of this communication. (35 U.S.C. § 133).		
Status				
1) ☐ Responsive to communication(s) filed on 4/21/2a) ☐ This action is FINAL . 2b) ☐ This 3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) See Continuation Sheet is/are pending 4a) Of the above claim(s) See Continuation Sheet 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 107-112 and 115-123 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	<u>eet</u> is/are withdrawn from conside	eration.		
Application Papers				
9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 2/3/06 is/are: a) ☐ access Applicant may not request that any objection to the confidence of Replacement drawing sheet(s) including the correction 11) ☐ The oath or declaration is objected to by the Example 11.	epted or b) \square objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date See Continuation Sheet.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate		

Continuation of Disposition of Claims: Claims pending in the application are 1,6-10,12-16,31,33,35,37-39,41,42,44,45,50,52,53,55,59,62,64-72,74-76,78,79,84,86,88-95 and 104-151. Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,6-10,12-16,31,33,35,37-39,41,42,44,45,50,52,53,55,59,62,64-72,74-76,78,79,84,86,88-95,104-106,113,114 and 124-151.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/3/06, 7/11/08, 11/21/08, 3/10/10, 11/17/10, 2/11/11, 5/17/11.

DETAILED ACTION

Election/Restrictions

1. Claims 1, 6-10, 12-16, 31, 33, 35, 37-39, 41, 42, 44, 45, 50, 52, 53, 55, 59, 62, 64-72, 74-76, 78, 79, 84, 86, 88-95, 104-106, 113, 114, 124-151 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/21/2011.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claim 108 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 108 recites the limitation "the expandable member" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the guidewire, sheath, looped tabs, rod or wire, and splittable jaws must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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6.

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 107-110, 112, 115, and 116 are rejected under 35 U.S.C. 102(b) as being anticipated by Berson US Patent 4246893.
- 9. Berson teach a method of treating obesity in a patient, the method comprising: making a percutaneous opening in the abdominal cavity of the patient (col. 4, lines 54-

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56); passing an expandable device (2), while in a contracted configuration, through the opening; positioning the expandable device (2) adjacent the stomach of the patient (col. 4, lines 56-59); expanding the expandable device (col. 5, lines 19-22); and anchoring the expandable device(2), relative to at least one structure in the abdominal cavity (the expandable device is anchored to the abdomen via port 4 by attaching sutures 28 to tub 3 and nozzle 9); further comprising anchoring (suturing tabs 33 to the abdomen) an adjustment member (4) that is connected to the expandable member (2) via a conduit (3), to a portion of the patient's body; wherein the positioning comprises positioning the expandable device anteriorly of the stomach to occupy a space normally occupied by the stomach (fig. 5).

Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. Claims 111, 117, and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berson '893.
- 12. As to claims 111, Berson discloses the claimed invention except for wherein at least two locations on the expandable device are anchored to at least one structure in the abdominal cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use more than one anchor, since it has been held that mere duplication of the essential working parts of a device involves only routine skill

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in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8. Therefore, it would have been obvious to one of ordinary skill in the art to anchor the expandable device in more than one location to keep the expandable device more securely placed adjacent the stomach.

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- 13. As to claims 117, Berson fails to teach wherein the method is performed as a laparoscopic procedure. However, it is well known in the art of abdominal surgery to use laparoscopic surgery as an alternative to open surgery because of advantages. Those advantages including reduced pain due to a smaller incisions, and shorter recovery time. Therefore it would have been obvious to one having ordinary skill in the art to perform the surgery using laparoscopy to reduce pain and shorten the recovery time of the patient.
- 14. As to claims 120, Berson discloses the claimed invention except for a second expandable member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use more than one anchor, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Therefore, it would have been obvious to one of ordinary skill in the art to use more than one expandable member as an alternative to a single expandable member to further compress the stomach.
- 15. Claims 119 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berson as applied to claim 115 above, and further in view of Grobe 5112310.

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16. Berson teaches the method of claims 115. It should be noted that Berson fails to teach the method steps of inserting a sheath and a guidewire.

- 17. Grobe teaches that the steps of inserting a sheath and a guidewire for gaining access to the stomach through the abdominal wall is well know in the art (introducer technique). Therefore, it would have been obvious to one having ordinary skill in the art to use a sheath and a guidewire to access the stomach through a small incision to reduce pain and shorten the recovery time of the patient as opposed to access via open surgery (col. 2, lines 3-13).
- 18. Grobe also teaches the method passing an expandable member within a sheath. It is well known in the art of surgical balloons to compact a balloon within a sheath for ease of delivery of a surgical balloon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. M./ Examiner, Art Unit 3734

/Gary Jackson/ Supervisory Patent Examiner Art Unit 3734